

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

Claim 1. (Currently amended) A pharmaceutical composition for topical administration, said composition consisting of:

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 1:1 to 1:3 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols

and polyhydric alcohols, wherein when the co-solvent comprises propylene glycol, the

propylene glycol is- present in an amount of less than -5% by weight; and

a propellant;

~~optionally one or more penetration agents selected from the group consisting of dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and~~

~~optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive;~~

wherein the apparent pH of the final product is in the range of from 5.0 to 7.0, and wherein the pharmaceutical composition contains one or more excipients suitable for forming a foam, aerosol, or mousse upon actuation with a propellant forms a foam or mousse.

Claim 2. (Cancelled)

Claim 3. (Previously presented) The pharmaceutical composition according to claim 1, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the pharmaceutical composition.

Claim 4. (Previously presented) The pharmaceutical composition according to claim 3, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claims 5-7. (Cancelled)

Claim 8. (Previously presented) The pharmaceutical composition according to claim 1, wherein the acid is acetic acid or lactic acid.

Claim 9-11. (Cancelled)

Claim 12. (Previously presented) The pharmaceutical composition according to claim 1, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 13. (Previously presented) The pharmaceutical composition according to claim 1, wherein the co-solvent is an alkylene glycol.

Claim 14. (Previously presented) The pharmaceutical composition according to claim 13, wherein the alkylene glycol is selected from one or more of the group consisting of glycerol, 1,3-butylene glycol and propylene glycol.

Claim 15. (Previously presented) The pharmaceutical composition according to claim 1, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 16. (Previously presented) The pharmaceutical composition according to claim 1, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claims 17-18. (Canceled)

Claim 19. (Previously presented) The pharmaceutical composition according to claim 1, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 20. (Canceled)

Claim 21. (Currently amended) A method for the treatment of hair loss and related indications in humans, comprising the steps of:

providing a pharmaceutical composition, consisting of
at least 5% by weight, based on the total weight of the composition, of minoxidil or
a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil
acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride,
minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active
present in the composition;
an acid in an amount to substantially completely solubilize the minoxidil or the

pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 1:1 to 1:3 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises propylene glycol, the propylene glycol is present in an amount of less than 5% by weight; and

a propellant:

optionally one or more penetration agents selected from the group consisting of dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive; and wherein the apparent pH of the final product is in the range of from 5.0 to 7.0, and the pharmaceutical composition contains one or more excipients suitable for forming a foam, aerosol, or mousse;

actuating the pharmaceutical composition with a propellant to form the pharmaceutical composition as a foam, aerosol, or mousse; and applying topically to the human scalp a therapeutically effective amount of the foam, aerosol, or mousse.

Claim 22. (Cancelled)

Claim 23. (Previously presented) The method according to claim 21, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 24. (Previously presented) The method according to claim 21, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the composition.

Claim 25. (Cancelled)

Claim 26. (Previously presented) The pharmaceutical composition according to claim 1,

wherein the lower alcohol is ethanol.

Claims 27-138. (Cancelled)

Claim 139. (Previously presented) The pharmaceutical composition according to claim 8,
wherein the acid is lactic acid.

Claim 140. (Previously presented) The pharmaceutical composition according to claim 14,
wherein the alkylene glycol is glycerol.

Claims 141-142. (Canceled)

Claim 143. (Previously presented) The pharmaceutical composition according to claim 1,
wherein the propellant is selected from the group consisting of one or more hydrocarbons,
dimethyl ether, and a chlorofluorocarbon.

Claim 144. (Previously presented) The pharmaceutical composition according to claim 143,

wherein the propellant is one or more hydrocarbons.

Claim 145. (Canceled)

Claim 146. (Previously presented) The method according to claim 24, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claim 147. (Previously presented) The method according to claim 21, wherein the acid is acetic acid or lactic acid.

Claim 148. (Previously presented) The method according to claim 147, wherein the acid is lactic acid.

Claim 149. (Previously presented) The method according to claim 21, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 150. (Previously presented) The method according to claim 21, wherein the co-solvent is an alkylene glycol.

Claim 151. (Previously presented) The method according to claim 150, wherein the alkylene glycol is selected from one or more of the group consisting of glycerol, 1,3-butyleneglycol and propylene glycol.

Claim 152. (Previously presented) The method according to claim 151, wherein the alkylene glycol is glycerol.

Claim 153. (Previously presented) The method according to claim 21, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 154. (Previously presented) The method according to claim 21, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claim 155. (Previously presented) The method according to claim 21, wherein the lower alcohol is ethanol.

Claim 156-158. (Cancelled)

Claim 159. (Previously presented) The method according to claim 21, wherein the propellant is selected from the group consisting of one or more hydrocarbons, dimethyl ether, and a chlorofluorocarbon.

Claim 160. (Previously presented) The method according to claim 159, wherein the propellant is one or more hydrocarbons.

Claim 161. (Canceled)

Claim 162. (Previously presented) The pharmaceutical composition according to claim 1, wherein the composition is free of propylene glycol.

Claim 163. (Previously presented) The method according to claim 21, wherein the composition is free of propylene glycol.

Claim 164. (New) The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition forms a foam or mousse.

Claim 165. (New) The method according to claim 21, wherein the pharmaceutical composition forms a foam or mousse.

Claim 166. (New) A pharmaceutical composition for topical administration, said composition consisting of:

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;
a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 1:1 to 1:3 by volume; and
a propellant;
wherein the apparent pH of the final product is in the range of from 5.0 to 7.0, and wherein the pharmaceutical composition contains one or more excipients such that, upon actuation, the pharmaceutical composition forms a foam, aerosol, or mousse.

Claim 167. (New) The pharmaceutical composition according to claim 166, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the pharmaceutical composition.

Claim 168. (New) The pharmaceutical composition according to claim 167, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claim 169. (New) The pharmaceutical composition according to claim 166, wherein the acid is acetic acid or lactic acid.

Claim 170. (New) The pharmaceutical composition according to claim 166, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 171. (New) The pharmaceutical composition according to claim 166, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 172. (New) The pharmaceutical composition according to claim 166, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claim 173. (New) The pharmaceutical composition according to claim 166, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 174. (New) The pharmaceutical composition according to claim 166, wherein the lower alcohol is ethanol.

Claim 175. (New) The pharmaceutical composition according to claim 169, wherein the acid is lactic acid.

Claim 176. (New) The pharmaceutical composition according to claim 166, wherein the propellant is selected from the group consisting of one or more hydrocarbons, dimethyl ether, and a chlorofluorocarbon.

Claim 177. (New) The pharmaceutical composition according to claim 176, wherein the propellant is one or more hydrocarbons.

Claim 178. (New) The pharmaceutical composition according to claim 166, wherein the composition is free of propylene glycol.

Claim 179. (New) The pharmaceutical composition according to claim 166, wherein the

pharmaceutical composition forms a foam or mousse.

Claim 180. (New) A method for the treatment of hair loss and related indications in humans, comprising the steps of:

providing a pharmaceutical composition, consisting of at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 1:1 to 1:3 by volume; and

a propellant;

wherein the apparent pH of the final product is in the range of from 5.0 to 7.0, and the pharmaceutical composition contains one or more excipients suitable for forming a

foam, aerosol, or mousse;

actuating the pharmaceutical composition to form a foam, aerosol, or mousse; and

applying topically to the human scalp a therapeutically effective amount of the foam,

aerosol, or mousse.

Claim 181. (New) The method according to claim 180, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 182. (New) The method according to claim 180, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the composition.

Claim 183. (New) The method according to claim 182, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claim 184. (New) The method according to claim 180, wherein the acid is acetic acid or

lactic acid.

Claim 185. (New) The method according to claim 184, wherein the acid is lactic acid.

Claim 186. (New) The method according to claim 180, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 187. (New) The method according to claim 180, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 188. (New) The method according to claim 180, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claim 189. (New) The method according to claim 180, wherein the lower alcohol is ethanol.

Claim 190. (New) The method according to claim 180, wherein the propellant is selected

from the group consisting of one or more hydrocarbons, dimethyl ether, and a chlorofluorocarbon.

Claim 191. (New) The method according to claim 190, wherein the propellant is one or more hydrocarbons.

Claim 192. (New) The method according to claim 180, wherein the composition is free of propylene glycol.

Claim 193. (New) The method according to claim 180, wherein the pharmaceutical composition forms a foam or mousse.